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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,129	09/12/2003	Daniel J. Cooke	279.445US1	9076

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EXAMINER	
STOKLOSA, JOSEPH A	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/662,129	COOKE ET AL.	
	Examiner	Art Unit	
	JOSEPH STOKLOSA	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) [5]prior art under 35 U.S.C. 103(a).

4. Claims 1, 4, 16, 19-21 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bush (US 5,755,762).

5. Bush discloses an electro-medical system comprising a container (non-electrode portions of the lead are electrically insulated with an insulator 34, 35, 36, 37, which may be silicone rubber, polyurethane, or nonporous fluoropolymer tubing located between. the conductor and beneath the porous covering 10; see col. 5, lines 43-67. Examiner considers this tubing to be "a container") including an electrical device therein (Examiner considers the conductor to be "an electrical device;" see Fig. 2) and a porous first covering over the container (continuous porous covering 10), wherein the porous first covering includes a porous communication to the container (the pore size is chosen to be small enough to discourage tissue ingrowth but large enough that current can be delivered through the covering when the pores are filled with body fluid; see col. 3, lines 10-16). Bush discloses that the porous tubular covering may be made of various materials, including polyethylene (see col. 6, lines 1-13, especially line 5). Examiner considers this polyethylene to be the claimed "expanded ultra-high molecular weight polyethylene" since the material of Bush is characterized by pore sizes suitable to allow penetration of bodily fluids but small enough such that fibrous tissue ingrowth is reduced (see col. 6, lines 13-22).

6. Examiner interprets the polyethylene to inherently have an average molecular weight of 100,000 to 5,000,000 since polyethylene, such as linear low density polyethylene has a molecular weight in the 10^5 range and UHMWPE in the 10^6 range, therefore the use the general term polyethylene will sufficiently meet the limitations of the average molecular weight ranges.

7. In the alternative, it would have been obvious for one or ordinary skill in the art at the time the invention was made to modify the system with UHMWPE with average molecular weight from 100,000 – 5,000,000 since it has been held that discovering the optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

8. With regard to claim 4, Bush discloses the container to be completely covered in the porous covering as seen in Fig. 2, 10.

9. With respect to claim 16, Bush discloses a lead including a lead proximal end, a lead body, and a distal end including an electrode (electrodes 16 and 20), wherein lead includes a porous covering (continuous porous covering 10) that includes a porous communication to the lead, and wherein the porous covering includes a pore structure that repels in vivo fibrotic tissue ingrowth (the pore size is chosen to be small enough to discourage tissue ingrowth but large enough that current can be delivered through the covering when the pores are filled with body fluid; see col. 3, lines 10-16).

10. With respect to claims 19-20, Bush discloses a dielectric coating over at least one of the proximal end and the lead body (non-electrode portions of the lead are electrically insulated with an insulator 34, 35, 36, 37, which may be silicone rubber, polyurethane, or nonporous fluoropolymer tubing located between the conductors and beneath the porous covering 10; see col. 5, lines 43-67).

11. With respect to claim 21, Bush discloses that lead 12 may be one of a plurality of leads (see col. 2, line 66 - col. 3, line 2).

Claim Rejections - 35 USC § 103

12. Claims 1, 3-14, 16, and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Soukup et al. (US 6,704,604) in view of Bush as applied above.

13. Soukup et al. discloses a system and method for selectively promoting tissue ingrowth on, or adjacent to, an implantable medical device utilizing a layer or porous PTFE tubing or tape, with the pores having a pore size to either selectively prevent substantially all tissue in-growth and/or selectively promote tissue in-growth at predetermined locations (see Abstract). Soukup et al. discloses that the disclosed invention may be utilized on the enclosure/can of an implantable medical device (see col. 8, lines 1-10), which necessarily includes an electrical device housed therein. Because the layer(s) are porous, body fluids that are retained within the pores allow these layers to conduct electricity when the lead is implanted (see col. 5, lines 45-50). Soukup et al. discloses that the porous covering is constructed from porous PTFE, and thus fails to teach that the porous covering may include "expanded ultra-high molecular weight polyethylene." Bush discloses various materials-for a porous covering, including both PTFE and polyethylene (see col. 6, lines 1-13). Examiner considers the polyethylene to be the claimed "expanded ultra-high molecular weight polyethylene" since the material of Bush is characterized by pore sizes suitable to allow penetration of bodily fluids but small enough such that fibrous tissue ingrowth is controlled as desired (see col. 6, lines 13-22). It would have been obvious to one having ordinary skill in the

art to modify the porous covering of Soukup et al. such that it includes polyethylene as taught by Bush, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USQP 416.

14. With respect to claims 3, 5-7, 11, 16, Soukup et al. discloses a lead (i.e., leads 600 and 604 of Fig. 6) having a distal end including an electrode/coil (electrodes 602 and 604). Soukup et al. discloses several embodiments, including embodiments in which the electrode/coil is covered with a porous second covering (see, for example, col. 7, lines 8-65) and embodiments in which portions of the lead body itself is covered with a porous second coating (see, for example, col. 5, line 7 - col. 6, line 59). In each embodiment, one of the porous layers has a pore size to prevent substantially all tissue in-growth (i.e., layer 308 of Figs. 3 and 4 and the inner layer disposed around the defibrillation electrodes).

With respect to claims 8-9 and 19-20, Soukup et al. discloses that the lead may include a dielectric coating over the proximal end (see col. 6, lines 9-43). The dielectric coating may be formed of silicone or other biomedical materials.

With respect to claims 10 and 21, Soukup et al. discloses that the system further includes a plurality of leads (i.e., leads 600 and 604 of Fig. 6).

With respect to claims 4, 12-14 and 18, Soukup et al. discloses that the disclosed invention may be utilized on the enclosure/can of an implantable medical device (see col. 8, lines 1-10). Although it is not explicit that such a housing or can may be a

pacemaker or defibrillator, it is apparent from the disclosure that the invention relates to defibrillation and pace/sense applications (see col. 1, line 20 - col. 2, line 52).

15. It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the IMD can of Soukup et al. to include monitoring functionality as is well known in the art in order to provide more physiological pacing therapy, or in order to record such monitoring health data for later review by a physician.

16. Claims 15, 22, and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,704,604 ("Soukup et al.") in view of U.S. Patent No. 5,755,762 ("Bush"), as applied above, and further in view of U.S. Patent No. 5,562,715 ("Czura et al.").

17. As discussed above, Soukup et al. discloses that the disclosed invention may be utilized on the enclosure/can of an implantable medical device (see col. 8, lines 1-10). However, Soukup et al. fails to disclose a. dielectric coating over the metallic can, and a passageway through the dielectric coating to form an exposed portion of the container. Czura et al. teaches that both unipolar and bipolar stimulation are known in the art, and one may be preferable to the other in many cases (see col. 1, lines 9-67). Czura et al. teaches a pacemaker (10), the housing of which is constructed of a conductive material (see col. 3, line 65- col. 4, line 3) coated with a dielectric material such as silicone rubber or paralene (see col. 4, lines 4-11). Detachable tabs (28) are provided on each side of the pacemaker in order to allow a physician to selectively expose a portion of the

casing to serve as an indifferent electrode when it is desirable for the device to pace in a unipolar mode (see, for example, col. 3, lines 3-11). It would have been obvious to one having ordinary skill in the art at the time of applicant's invention to modify the pacemaker system of Soukup et also such that the can has a dielectric coating and detachable tabs for selectively exposing a portion of the can to serve as an indifferent electrode as taught by Czura et al. in order to enable the pacemaker system to operate in either a unipolar or bipolar mode, depending upon which stimulation mode is preferable.

18. With respect to claims 24-26, Soukup et al. discloses a lead (i.e., leads 600 and 604 of Fig. 6) having a distal end including an electrode/coil (electrodes 602 and 604). Soukup et al. discloses several embodiments, including embodiments in which the electrode/coil is covered with a porous second covering (see, for example, col. 7, lines 8-65) and embodiments in which portions of the lead body itself is covered with a porous second coating (see, for example, col. 5, line 7 - col. 6, line 59). In each embodiment, one of the porous layers has a pore size to prevent substantially all tissue in-growth (i.e., layer 308 of Figs. 3 and 4 and the inner layer disposed around the defibrillation electrodes).

Response to Arguments

19. Applicant's arguments filed 12/10/2007 have been fully considered but they are not persuasive.

20. Applicant argues that Bush teaches away from the use of polyethylene by discloses PTFE as a preferred material. Applicant is incorrect in making the assertion that Bush teaches away from use of polyethylene by discloses PTFE as a preferred material. MPEP 2145 states "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed…." In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004) and pursuant to MPEP 2123 "a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments." Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). Accordingly Bush does not criticize, discredit, or otherwise discourage the use of polyethylene by discloses a preferred embodiment of PTFE and Bush's non preferred embodiment meets the claimed limitation.

21. Applicant has argued that the mere disclosure of the use of polyethylene fails to anticipate a molecule of MW range 100,000 – 5,000,000. Examiner maintains the position that the general disclosure of polyethylene encompasses well known linear low density polyethylene MW from 10^5 to higher molecular weight polyethylene of ~$3x10^6$-$6x10^6$ MW.

22. Applicant argues the improper use of official notice to determine a workable range for the molecular weight of a material and the workable range being directed to choosing a type of material rather than discovering the optimum range. Examiner did

not take official notice, but rather simply supported a 103 rejection based on common knowledge in the art and legal precedent. See MPEP 2144 "The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992)." Further it is of note that it was proper to make a rejection on the obvious range of a material and not that actual material. See MPEP 2144.05 In re Hoeschele, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969) (Claimed elastomeric polyurethanes which fell within the broad scope of the references were held to be unpatentable thereover because, among other reasons, there was no evidence of the criticality of the claimed ranges of molecular weight or molar proportions.).

Conclusion

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Stoklosa whose telephone number is 571-272-1213. The examiner can normally be reached on Monday-Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

Joseph Stoklosa
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2/21/2008